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<b>RESPONSE</b>			Docket No. <b>HUM221USPT01</b>
Serial No. <b>09/683,070</b>	Filing Date <b>November 15, 2001</b>	Examiner <b>Deborah K. Ware</b>	Group Art Unit <b>1642</b>
Applicant:	<b>Henn</b>		
Invention:	<b>TREATMENT OF MENORRHAGIA, HYPERMENORRHEA, DYSMENORRHEA AND MENSTRUAL MIGRAINES BY THE ADMINISTRATION OF AN ANTIBACTERIAL MILK PRODUCT</b>		

Commissioner of Patents  
Washington, D.C. 20231

This Response is being filed in reply to the Office Action mailed September 23, 2003 to which a response is due on or before December 23, 2003.

No claims have been amended. No claims have been canceled. No new claims have been added. Claims 1-20 remain pending in the application.

Applicant thanks the Examiner for indicating that the claims are patentable over the prior art of record.

**General Objections/Rejections**

**1.0** *The Examiner has objected to the Abstract as insufficiently descriptive of the claimed invention.*

Applicant respectfully submits that the Abstract accurately describes the invention as claimed. Should the Examiner continue to believe that the Abstract is insufficiently descriptive of the claimed subject matter, Applicant requests an indication of the specific aspect(s) considered to be insufficiently described in the Abstract.

**Objections/Rejections  
Under 35 U.S.C. § 112**

**2.0** *The Examiner has rejected claims 1-20 under 35 U.S.C. §112, first paragraph as nonenabled for failure to deposit or otherwise enable others to obtain the microorganisms used to produce the antibacterial milk product used in the claimed method of treatment.*

The present claimed method of treatment involves administration of an antibacterial milk product to a female mammal suffering from menorrhagia, hypermenorrhea, dysmenorrhea or menstrual migranes. It is expressly noted that the present claimed invention is NOT directed to novel microorganisms NOR novel products obtained from microorganisms. Rather, the present claimed invention is directed to a new use of known products obtained by a known process from known microorganisms.

The present application discloses at paragraph [0031] that, "Concentrated antibacterial powdered skimmed milk, manufactured in accordance with the process described above and useful in the treatment of menorrhagia, hypermenorrhea, dysmenorrhea and menstrual migraines in accordance with the treatment method disclosed herein, is commercially available from AdvantRx Corporation of Chanhassen, Minnesota and Stolle Milk Biologics, Inc. of Cincinnati, Ohio under the mark MICROLACTIN™. Since antibacterial milk products useful in the present claimed method of treatment are commercially available, the present application is enabled as to the claimed subject matter of the application.

Furthermore, in the event an enabling disclosure of the microorganisms is still considered necessary, Applicant submits that the present application includes an enabling disclosure of the microorganisms. The present application discloses at paragraph [0015] that, "Antibacterial milk, from which various antibacterial milk products can be extracted, can be produced in accordance with the process set forth in United States Reissue Patent No. Re. 33,565, the disclosure of which is hereby incorporated by reference". United States Reissue Patent No. Re. 33,565 (the "Reissue Patent") provides an enabling disclosure of the microorganisms used to produce the antibacterial milk products claimed in that patent. The antibacterial milk products used in the present claimed method of treatment are those produced in accordance with the process set forth in the Reissue Patent. Since the disclosure of the Reissue Patent is incorporated by reference into the present application, the present application also provides an enabling disclosure of the microorganisms used to produce the antibacterial milk products used in the present claimed method of treatment.

Withdrawal of this rejection is respectfully requested.

**3.0** *The Examiner has rejected claims 1, 2, 6, 7, 11, 12, 16 and 17 under 35 U.S.C. §112, second paragraph as indefinite for use of the overly broad term "administering".*

The primary purpose for the requirement of definiteness in claim language is to ensure that the public is adequately informed of the metes and bounds of the patented invention. See, M.P.E.P. §2173.

The examination of claims for definiteness under 35 U.S.C. §112, second paragraph must focus upon whether the claim meets the threshold requirements of clarity and precision, NOT whether more suitable language or modes of expression are available. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. If the scope of the subject matter embraced by the claims is clear, and applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, the claims comply with 35 U.S.C. §112, second paragraph. M.P.E.P. §2173.04 [BREADTH IS NOT INDEFINITENESS]. Breadth

of a claim is NOT to be equated with indefiniteness. In re Miller, 441 F.2d 689, 159 USPQ 597 (CCPA 1971).

Applicant concedes that the claimed element "administering" is a broad term encompassing numerous routes. Such breadth is intentional. Applicant has discovered that the conditions of menorrhagia, hypermenorrhea, dysmenorrhea and menstrual migranes may be treated by the administration of an antibacterial milk product. The scope of the invention conceived by Applicant is NOT limited by the specific route of administration. Various routes by which the antibacterial milk product may be administered are set forth in the application at paragraphs [0032] - [0040]. Applicant respectfully submits that the broad terminology used in the claims is clear and precise. The public is clearly advised by the claim language as to the boundaries of the claimed invention.

Withdrawal of this rejection is respectfully requested.

#### CONCLUSION

Applicant respectfully submits that all pending claims (claims 1-20) are in condition for allowance.

Respectfully submitted,

Date 04-Dec-03

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